REMARKS

Claims 1,11,18 and 32 have been amended to make it clear that the amino acid component of the composition is only an isoleucine compound or active analog of isoleucine.

Support for this amendment can be found in the paragraph bridging pages 2 and 3 of the specification and lines 12-15 on page 2 thereof.

Claim 11 has also been amended to specify the component B) pharmacologically active substances that can be present in the composition (see pages 7-15 of the specification).

New claim 41 has been added to limit the epithelial surface being treated to one or more of the oral cavity, GI tract, genitourinary tract, skin, and eye.

New claim 42 has been added to give a range for the quantity of the amino acid component in the composition of claim 1 (for 100% upper end of the range, see page 8, lines 19 and 20).

Claim 6 has been amended to include the pharynx (see page 3 line 8 of the specification).

New claims 43 and 44 have been added to specify treatment of microbial infection (claim 43) and specifically a bacterial infection (claim 44).

Claims 1-16,18,25,31,32 and 34 have been rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enabling requirement.

This contention is respectfully controverted.

The isoleucine stereoisomers and active analogs thereof, used in the practice of the invention are set forth in the paragraph bridging pages 2 and 3 .

The microbial blocking quantities that can be used to obtain this effect are set forth in lines 16-19 on page 2. Any physician using isoleucine can readily determine the dosage quantity needed to obtain the above microbial blocking quantities. Moreover, with all medications, titration of dosage to obtain an effective quantity for a particular patient is standard medical procedure.

In addition, on page 7, first paragraph, a readily implemented method for determining an effective dose of isoleucine is set forth in clear and easily understood language.

Furthermore, dosage forms for administration of isoleucine are set forth throughout the specification; see e.g. pages 7-15, including the use of isoleucine as the only pharmacologically active component (page 8, lines 19 and 20).

Hence, it is contended that the enablement requirement of section 112 has been fully met.

The Examiner's consideration of factors to be considered include the following:

> (2) The state of the prior art. The Examiner's statement of the teachings of the prior art is not believed to be correct and will be discussed in detail with respect to the section 103 rejections.
>
> (3) Since the Examiner agrees that the relative skill of those in the art is high, those skilled in the art would have no problems with enablement for the reasons discussed above.
>
> (4) The Examiner's statement that the predictability of the art is high and

the reasons given therefor are again not believed to be correct and will be discussed with respect to the section 103 rejections.

(5) The claims, except for new claim 44, are broad with respect to blocking microbial adherence to eukarytic cells, since blocking the cell surfaces will prevent any microbe from attaching to the cells, and therefore the invention is broad with respect to microbe blocking. Moreover, the Examples show effectiveness of the present method with respect to various types of bacteria. See e.g. Examples 1 and 4. Also, the invention functioned effectively even where the nature of the infectious agent was unknown. See Example 2 (infectious diarrhea) and Example 3 (irritable bowel syndrome).

(6) The Examiner questions how isoleucine can treat or prevent an entire group of microbes. Treatment or prevention of microbial adherence to cell surfaces is obtained by the blocking action of isoleucine. The Examiner contends that "preventing" on page 5, line 8 implies a cure. It is not agreed that a cure is implied. See e.g. Example 3 where isoleucine was effective in relieving irritable bowel syndrome, a condition for which the etiology is unknown. Each individual was maintained on isoleucine for 1 month with a consistent response. Yet, when isoleucine was withdrawn, former symptoms reappeared. Hence, the individuals were not "cured" nor is there any statement in the specification suggesting or stating that the method of the invention provides a cure.

(7) The working examples, although limited in patient numbers, showed

that in every case the treatment was effective over a wide range of conditions. These examples are of course not based on extensive clinical trials with large numbers of subjects, but this does not take away from the fact that in every case and every condition tested, the present method was effective. Applicant is not required by any law or practice to present extensive clinical studies such as those required for a New Drug Application.

(8) It is not agreed that undue or painstaking experimentation would be required to determine effectiveness for a particular microbe - isoluecine would be administered to the affected cells at a dosage set forth in the specification and the effect on the patient or patients evaluated, which is in fact a standard medical procedure.

On page 5 of the Office Action, the Examiner states that no specific formulations, specific amounts and specific procedures or administration are set forth. The Examiner's conclusion is not agreed with for all the reasons discussed above.

Claims 1-16,18 and 25 have been rejected under 35 U.S.C. 103 (a) as being unpatentable over the Pedersen reference (U.S. 6,607,711 B2)

As noted by the Examiner, Pedersen's compositions require the use of chelates of a metal ion, in which it is the metal ion that reduces microbial growth potential. The metal chelate is described on page 13 (of my web site copy) as "The resulting molecule has two or three five-membered heterocyclic ring structures containing a metal ion attached by coordinate covalent bonds to two or more non-metals in the same molecule. properties such as e.g. the nature of the chemical bonds involved in forming the different

chemical structures."

The two paragraphs following this quotation make it additionally clear that the chelate is not an amino acid salt.

Hence, the amino acids used to form the chelates are reaction products only and do not exist as such in the chelate. Isoleucine does not have "two or three five-membered heterocyclic ring structures".

Hence, it is respectfully contended that the chelate of Pedersen is chemically unrelated to isoleucine,and functions by an entirely different mechanism, i.e. metal ion toxicity to microbes.

Also, as noted by the Examiner, Pedersen does not teach Applicant's claimed ranges. As discussed above, the compounds used in the respective inventions are chemically quite dissimilar, and hence their respective ranges are respectfully submitted to be irrelevant. Moreover, since both the products and mechanisms of action are unrelated, any test of discovery "optimum or workable ranges "cannot apply here.

Claims 1-13, 18,25,31,32 and 34 have been rejected under 35 U.S.C. 103(a) as being unpatentable over the Zeng reference (U.S. 6,770,306 B1).

The Examiner has interpreted the present claims as permitting mixtures of amino acids, and refers to isoleucine as a preferred amino acid. This assumption is not accurate, since the present inventors have found that isoleucine, and only isoleucine and its stereoisomers and active analogs, have the unexpected benefits of blocking eukaryotic cell surfaces to prevent or at least significantly decrease microbial attachment to such cell surfaces. Accordingly, independent claims 1,11,18, and 32 have been amended to limit

the amino acid component to isoleucine and its analogs. Also, claim 1 component B) excludes other amino acids as an additional pharmacologically active substance.

Hence, the claims as amended exclude mixtures of amino acids, which are always used by Zeng (see e.g. claim 1 where nine amino acids are present, claim 2 where eight amino acids are present, etc.).

Moreover, Zeng's compositions containing amino acid mixtures are used to treat vaginitis resulting from highly acidic vaginas, i.e. as neutralizing agents. This disclosure has nothing to do with a method for blocking microbial adherence to eukaryotic cell surfaces (claims 1-10 and 41-44).

With respect to composition claims 11-16, 17,25,31,32 and 34, as discussed above, claim 11 has been amended to limit the amino acid component to isoleucine steroisomers and active isoleucine analogs, and component B) does not include other amino acids. Moreover, claims 16,18,31,32 and 33 relate to toothpastes or gels or wound or skin ointments or creams, clearly not disclosed by Zeng.

With respect to the amounts of isoleucine, as noted by the Examiner, Zeng does not teach Applicant's ranges of microbial blocking quantities for cell surfaces recited in claims 2-4. The argument re finding suitable ranges is not relevant since the use of amino acid mixtures as neutralizing agents has nothing to do with the blocking of cell surfaces to block microbial adherence.

In view of the amendments to the claims and the above discussion, it is respectfully contended that (a) the claims (particularly as amended) are free from section 103 rejections over the prior art, and (b) that the specification is fully enabling under section 112.

Allowance of claims 1-16,18,25,31,32, 34 and 41-44 is respectfully requested.

Respectfully submitted,

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